

In the claims:

1. (Original) A method of enhancing an immune response to an antigen in a mammal, comprising administering to the mammal a safe and effective amount of 1) an IL-18 polypeptide or bioactive fragment or variant thereof, and 2) an immunogenic composition comprising an antigen or immunogenic derivative thereof and a saponin adjuvant.

2. (Previously amended) A method according to claim 2, wherein the antigen or immunogenic derivative thereof is derived from an organism selected from the group of Human Immunodeficiency virus HIV-1, human herpes simplex viruses, cytomegalovirus, Rotavirus, Epstein Barr virus, Varicella Zoster virus, from a hepatitis virus such as hepatitis B virus, hepatitis A virus, hepatitis C virus and hepatitis E virus, from Respiratory Syncytial virus, parainfluenza virus, measles virus, mumps virus, human papilloma viruses, flaviviruses or Influenza virus, from Neisseria spp, Moraxella spp, Bordetalla spp; Mycobacterium spp, including M. tuberculosis; Escherichia spp, including enterotoxic E. coli; Salmonella spp,; Listeria spp; Helicobacter spp; Staphylococcus spp., including S. aureus, S. epidermidis; Borrelia spp; Chlamydia spp., including C. trachomatis, C. pneumoniae; Plasmodium spp., including P. falciparum; Toxoplasma spp., and Candida spp.

3. (Previously amended) A method of reducing the severity of a cancer in a patient, comprising administering to a patient in need thereof a safe and effective amount of 1) an IL-18 polypeptide or bioactive fragment or variant thereof and 2) an immunogenic composition comprising a tumour-associated antigen or immunogenic derivative thereof and a saponin adjuvant.

4. (previously amended) A method according to claim 3, wherein the tumour-associated antigen or immunogenic derivative thereof is selected from the group of: an antigen from the MAGE family, PRAME, BAGE, LAGE 1, LAGE 2, SAGE, HAGE, XAGE, PSA, PAP, PSCA, prostein, P501S, HASH2, Cripto, B726, NY-BR1.1, P510, MUC-1, Prostase, STEAP, tyrosinase, telomerase, survivin, CASB616, P53, and her 2 neu.

5. (previously amended) The method according to claim 1, wherein the IL-18 polypeptide or bioactive fragment or variant thereof and the immunogenic composition are administered simultaneously, separately or sequentially in any order.

6. (previously amended) The method according to claim 5 wherein the IL-18 polypeptide or bioactive fragment or variant thereof and the immunogenic composition are administered simultaneously in the form of a combined pharmaceutical preparation.

7. (Previously amended) The method according to claim 1, wherein the IL-18 polypeptide or bioactive fragment or variant thereof is from human or murine origin.

8. (previously amended) The method according to claim 7, wherein IL-18 is the polypeptide of SEQ ID NO:6 or SEQ ID NO:7 or bioactive fragment or derivative thereof.

9. (previously amended) The method according to claim 1 wherein the saponin adjuvant is chosen from the group of: QS-21 and QS-17.

10. (Currently amended) A kit combined preparation comprising as active ingredients the following individual components: (1) a pharmaceutical preparation of IL-18 polypeptide or bioactive fragment or variant thereof and (2) an immunogenic composition comprising an antigen and a saponin adjuvant, the active ingredients being for the simultaneous, separate or sequential use for the prophylaxis and/or treatment of infectious diseases, cancer, autoimmune diseases and related conditions.

11. (Currently amended) The kit combined preparation according to claim 10, wherein components (1) and (2) are admixed in a pharmaceutical composition.

12. (Currently amended) The kit combined preparation according to claim 10, wherein the immunogenic composition comprises a tumour-associated antigen or immunogenic derivative thereof and is prophylactically or therapeutically active against cancer.

13. (Currently amended) The kit combined preparation according to claim 12, wherein the tumour-associated antigen or immunogenic derivative thereof is selected from the group of an antigen from the MAGE family, PRAME, BAGE, LAGE 1, LAGE 2, SAGE, HAGE, XAGE, PSA, PAP, PSCA, prostein, P501S, HASH2, Cripto, B726, NY-BR1.1,

~~P510, MUC-1, Prostase, STEAP, tyrosinase, telomerase, survivin, CASB616, P53, and her 2 neu.~~

14. (currently amended) The kit combined preparation according to claim 10 wherein the IL-18 polypeptide ~~or bioactive fragment or variant thereof~~ is from human or murine origin.

15. (currently amended) The kit combined preparation according to claim 14 wherein ~~the IL-18 is the polypeptide consists of SEQ ID NO:6 or SEQ ID NO:7 or bioactive fragment or derivative thereof.~~

16. (currently amended) The kit combined preparation according to claim 10 wherein the saponin adjuvant is chosen from the group of: QS-21 and QS-17.

17. (currently amended) The kit combined preparation as claimed in claim 10, wherein the immunogenic composition additionally comprises an ~~immunostimulant chemical selected from the group of: 3D-MPL, cholesterol, CpG oligonucleotide containing at least one immunostimulatory CG dinucleotide, aluminium hydroxide, aluminium phosphate, and tocopherol, and an oil in water emulsion or a combination of two or more of the said adjuvants.~~

18. (currently amended) The kit combined preparation as claimed in claim 17, wherein the immunogenic composition adjuvant comprises 3D-MPL, QS21, cholesterol, and an oil in water emulsion.

19. (currently amended). The kit combined preparation as claimed in claim 18, wherein the oil in water emulsion comprises squalene, tocopherol, and polyoxyethylenesorbitan monooleate (Tween-80).

20. (cancelled)

21. (currently amended) The kit combined preparation as claimed in claim 10, wherein said pharmaceutical preparation of IL-18 and said immunogenic composition are both active components are in the form of injectable solutions.

22. (previously amended) A pharmaceutical kit comprising as active ingredients : (1) an IL-18 polypeptide or bioactive fragment thereof, and 2) an immunogenic composition comprising an antigen or immunogenic derivative thereof and a saponin adjuvant, the active ingredients being for the simultaneous, separate or sequential use for the prophylaxis and/or treatment of infectious diseases, cancer, and auto-immune diseases.

23. (previously amended) The pharmaceutical kit according to claim 22, wherein the immunogenic composition comprises a tumour-associated antigen or immunogenic derivative thereof and is prophylactically or therapeutically active against cancer.

24. (previously amended) The pharmaceutical kit according to claim 23, wherein the tumour-associated antigen or immunogenic derivative thereof is selected from the group of: an antigen from the MAGE family, PRAME, BAGE, LAGE 1, LAGE 2, SAGE, HAGE, XAGE, PSA, PAP, PSCA, prostein, P501S, HASH2, Cripto, B726, NY-BR1.1, P510, MUC-1, Prostase, STEAP, tyrosinase, telomerase, survivin, CASB616, P53, and her 2 neu.

25. (cancelled)

26. (previously amended) The method as claimed in claim 1, which comprises the use of a combined preparation according to claim 10.

27. – 32. (cancelled)

33. (Previously presented) A method for the prophylaxis and/or treatment of a patient suffering from or susceptible to infectious diseases, cancer, autoimmune diseases and related conditions, and already primed with an immunogenic composition, comprising an antigen or immunogenic derivative thereof and a saponin adjuvant, comprising administering to the patient a safe and effective amount of an IL-18 polypeptide or bioactive fragment thereof.

34. (cancelled)

35. (previously presented) The method according to claim 33, wherein the antigen is a tumour-associated antigen, and the cancer is selected from the group of: breast cancer, lung

cancer, NSCLC, colon cancer, melanoma, ovarian cancer, bladder cancer, head and neck squamous carcinoma, and esophageal cancer.

36. (previously presented) The method according to claim 33, wherein the IL-18 polypeptide or bioactive fragment or variant thereof is from human or murine origin.

37 (previously presented) The method according to claim 36, wherein IL-18 is the polypeptide of SEQ ID NO:6 or SEQ ID NO:7 or bioactive fragment or derivative thereof.

38. (previously presented) The method according to any claim 33, wherein the saponin adjuvant is chosen from the group of: QS-21 and QS-17.